K133607

LIBRAMEDICAL

FEB 11 2014

7. 510(K) SUMMARY

7.1 ADMINISTRATIVE INFORMATION

Date of Summary Preparation: November 22, 2013

7.1.1 Contact Information

Submitter/Manufacturer	Mark Ungs InterValve, Inc. 16200 State Highway 7, Unit B Minnetonka, MN 55345 Phone: 952-303-3539 Fax: 952-303-6310 Email: mark@intervalveinc.com
Primary Submission Contact	Julie Bodmer Regulatory Consultant, Libra Medical Inc. 8401 73rd Ave North, Suite 63 Minneapolis, MN 55428 Phone: 612-910-3412 Fax: 763-477-6357 Email: jbodmer@libramed.com
Secondary Submission Contact	Sew-Wah Tay, PhD Regulatory Consultant, Libra Medical Inc. 8401 73rd Ave North, Suite 63 Minneapolis, MN 55428 Phone: 612-801-6782 Fax: 763-477-6357 Email: swtay@libramed.com

7.1.2 Device Information

Trade Name	V8
Common Name	Balloon Aortic Valvuloplasty Catheter
Classification Name	Catheter, Balloon Aortic Valvuloplasty
Classification Regulation	870.1255
Class	II
Panel	Cardiovascular
Product Code	OZT
FDA Documents Related to Modified Device	None

7.2 PREDICATE DEVICE

The modified device is substantially equivalent to the InterValve V8 Transluminal BAV Catheters (K123111 and K132728) and the NuMED NuCLEUS-X BAV Catheter (K082776).

7.3 DEVICE DESCRIPTION

The V8 Transluminal BAV Catheter System features a figure-8 shaped dilatation balloon on the distal end of a catheter. The catheter is inserted through a percutaneous entry site into the common femoral artery via an introducer sheath and advanced retrograde to the aortic valve. The catheter is always delivered over a guidewire. The balloon is then inflated to dilate the stenotic aortic valve leaflets in an effort to increase valve opening dimensions and systemic blood flow by improving leaflet mobility. The figure-8 shaped balloon with the undersized waist segment is intended to minimize over-dilatation of the valve annulus while allowing the full dilation of the valve leaflet. The bulbous proximal balloon segment is appropriately sized for the patient's aortic root dimensions to maximize valve leaflet opening.

7.4 INDICATIONS FOR USE/INTENDED USE

The V8 Transluminal BAV Catheter is indicated for Balloon Aortic Valvuloplasty.

There is no change in intended use. The indication for use and intended use are identical to the predicate device.

7.5 TECHNOLOGICAL CHARACTERISTICS

The modified V8 balloon is made of clear semi-compliant polymeric material. The balloon is available in four sizes (waist diameters 17mm, 19mm, 21mm and 23mm). Similar to the predicate V8 devices, this balloon is designed such that the waist diameter is smaller than the bulb diameter. The V8 balloon is intended to provide a means for dilation of stenotic aortic valve leaflets while minimizing dilation of the aortic annulus by virtue of its figure-8 shape.

The catheter is available in standard working lengths (107cm – 113cm) and is compatible with a 12F introducer sheath. It is introduced through the femoral artery via the introducer sheath and tracked over a 0.035" wire. The catheter's inner shaft beneath the balloon is marked with radiopaque platinum iridium marker bands, one at the center of the waist, and one each at the outside edges of the proximal and distal balloon shoulders. The band at the middle is approximately twice the width as the bands at each shoulder. The catheter is packaged in a heat sealed Tyvek pouch and provided sterilized. It is intended for single use only. These characteristics are identical to the predicate V8 devices.

7.6 PERFORMANCE DATA

The V8 BAV Catheter is subject to special controls per 510(k) approval summary K082776. Table 7-1 describes the evidence that shows the V8 BAV Catheter meets all special control requirements listed for BAV devices.

Table 7-1: Special Controls

Special Control Requirement	Evidence of Conformity
The device should be demonstrated to be biocompatible.	The proposed change does not affect the biocompatibility of the device. The biocompatibility test data were provided in the K123111. There were no new materials added.
Sterility and shelf life testing should demonstrate the sterility of patient-contacting components and the shelf-life of these components.	The sterile packaging and shelf carton are identical to the predicate V8 devices. The worst case device is identical to the predicate device. Therefore the sterility data provided previously is applicable. The sterilization validation test results provided in the predicate 510(k) notification K123111 are applicable to this device. Aging data for the sterile barrier seal was also provided in the predicate device submission. Shelf life testing was repeated and provided in this submission.
Non-clinical performance evaluation of the device should demonstrate substantial equivalence in terms of safety and effectiveness for device delivery, inflation, deflation, and removal.	Design verification testing was repeated and provided in this submission. Delivery, inflation, deflation, and removal data is provided with the DV report in section 16 of the submission.
In vivo evaluation of the device should demonstrate device performance, including the ability of the device to treat aortic stenosis.	The general shape of the device has not changed and the principles of operation are also the same. The device dimensions are identical to the predicate device submitted in 510(k) notification K132728.
Labeling must include a detailed summary of the device-related and procedure-related complications pertinent to use of the device.	The IFU contains "Potential Complications, Outcomes, Adverse Events" section.

The relevant design verification and shelf life tests were performed before and after accelerated aging, respectively. Testing included:

- Balloon rated burst pressure
- Balloon compliance
- Critical dimension verifications
- Guidewire and introducer compatibility
- Deflation times
- Repeat inflation
- Leak
- Tensile
- Kink
- Torque

The design verification and shelf life testing showed that the device meets its specifications both before and after aging. This indicates that the device is as safe and effective as the predicate V8 devices.

7.7 SUBSTANTIAL EQUIVALENCE

The V8 device covered by this submission is substantially equivalent to the predicate devices. The device intended use has not changed and the overall design principles are the same. The balloon material in this modification is similar to the balloon materials in the predicate devices in that all these balloons are a type of polyamides, or generically called nylon.

The compliance of the balloon in this submission is similar to the predicate V8 Nylon balloons (K123111 and K132728) and the Nucleus-X PES2 balloon (K082776). All these BAV balloons are polyamides, and all the dimensions of these balloons increase with increased inflation volume or pressure. The modified V8 device is designed to reach the nominal dimensions at a lower pressure than its predicates.

The slight changes in balloon geometry and compliance are within the bounds of the original V8 balloon dimensions, and the nominal dimensions are identical to the V8 described in K132728, and have the same technical characteristics of the cleared predicate V8 balloons.

The new design does not change the biocompatibility of the device. All materials in direct body fluid contact are the same as the predicate V8 devices.

The V8 device covered by this submission has the same intended use and the same technological characteristics as the previously cleared predicate devices. The differences between this device and its predicates do not raise new questions of safety or efficacy.

7.8 CONCLUSION

The modified V8 Transluminal BAV Catheter System is substantially equivalent to the predicate devices (K123111, K132728 and K082776) in design, technological characteristics, materials, function and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 11, 2014

Intervalve, Inc..
c/o Ms. Julie Bodmer
Regulatory Consultant
Libra Medical Inc.
8401 73rd Avenue North, Suite 63
Minneapolis, MN 55428

Re: K133607
Trade/Device Name: Intervalve V8 transluminal BAV Catheter
Regulation Number: 21 CFR 870.1255
Regulation Name: Ballon Aortic Valvuloplasty Catheter
Regulatory Class: Class II (two)
Product Code: OZT
Dated: December 17, 2013
Received: December 18, 2013

Dear Ms. Bodmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

6. INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K133607

Device Name: V8 Transluminal BAV Catheter

Indications for Use:
The V8 Transluminal BAV Catheter is indicated for Balloon Aortic Valvuloplasty.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)